

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC. and	)	
PENWEST PHARMACEUTICALS CO.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 07-731 (***)
	)	
IMPAX LABORATORIES, INC.,	)	
	)	
Defendant.	)	

**PLAINTIFFS' REPLY TO DEFENDANT'S COUNTERCLAIMS**

Plaintiffs/counterclaim defendants Endo Pharmaceuticals Inc. ("Endo") and Penwest Pharmaceuticals Co. ("Penwest") (collectively, "Plaintiffs"), for their reply to the Answer and Counterclaims filed by defendant/counterclaim plaintiff Impax Laboratories, Inc. ("Impax"), upon knowledge as to their own acts, and upon information and belief as to all other matters, hereby respond and allege as follows:

**REPLY TO DEFENDANT'S COUNTERCLAIMS**

71. Plaintiffs repeat and reallege their allegations with respect to paragraphs 1 to 46 and 57-66 of their Complaint as if set forth at length herein.

72. Denied as stated. Impax's Paragraph IV Notices 1 -- 6 (as defined in Plaintiffs' Complaint) are null, void and without legal effect. Therefore, no actual case or controversy properly exists with respect to issues concerning the infringement and validity of United States Patent Nos. 5,662,933 ("the '933 patent") and 5,958,456 ("the '456 patent") based on those Notices. Impax, however, refused to withdraw Notices 1-6, and as a result, Plaintiffs were improperly forced to file this action to preserve their rights under the Hatch-Waxman Act. Impax subsequently served a Paragraph IV Notice on December 13, 2007 (*i.e.*, after the FDA deemed Impax's amended ANDA No. 79-087 acceptable for filing as of November 23, 2007).

However, pursuant to 35 U.S.C. § 271(e)(5), Impax is not entitled to assert any declaratory judgment counterclaims based on the December 13 Notice, because this action is based on Impax's Paragraph IV Notices 1 – 6 and because the 45-day period in which Plaintiffs may file suit based on the December 13 Notice has not yet run. By way of further answer, Plaintiffs deny that Impax's commercial manufacture, offer for sale or sale of its proposed generic oxymorphone hydrochloride extended-release tablets would not infringe the '456 and '933 patents, deny that either the '456 or the '933 patent is invalid, and deny the remaining allegations and implications of this paragraph.

#### **PARTIES**

73. Admitted.

74. Admitted.

75. Admitted.

#### **JURISDICTION AND VENUE**

76. Denied as stated. Plaintiffs incorporate their reply to paragraph 72 as if fully set forth herein. Plaintiffs deny that Impax is entitled pursuant to 35 U.S.C. § 271(e)(5) to assert any declaratory judgment counterclaims at this time with respect to the infringement and validity of the '456 or the '933 patent, and deny therefore that this Court presently has jurisdiction over any such counterclaims. Plaintiffs further deny the remaining allegations and implications of this paragraph.

77. Admitted in-part and denied in-part. Plaintiffs admit that this Court has personal jurisdiction over them, and that venue would be proper in this Court for Impax's counterclaim if this Court had subject matter jurisdiction over it. Plaintiffs deny the remaining allegations and implications of this paragraph.

**DEFENDANT'S COUNTERCLAIM**

78. Plaintiffs repeat and reallege their allegations and responses with respect to paragraphs 1 to 46 and 57-66 of their Complaint and paragraphs 71-77 of this Reply as if set forth at length herein.

79. Denied as stated. Plaintiffs incorporate their reply to paragraphs 72 and 76 as if fully set forth herein. Plaintiffs further deny any contention that Impax's commercial manufacture, offer for sale or sale of its proposed generic oxymorphone hydrochloride extended-release tablets would not infringe the '456 and '933 patents, deny that either the '456 or the '933 patent is invalid, and deny the remaining allegations and implications of this paragraph.

80. Admitted in-part and denied in-part. Plaintiffs admit that they filed the Complaint that commenced this suit on November 15, 2007, that as alleged therein, Penwest is the assignee and owner of the '456 and '933 patents, and that Endo is an exclusive licensee of these patents in the relevant field of use pursuant to a strategic alliance agreement with Penwest. Plaintiffs further admit that, as alleged in their Complaint, the '456 and '933 patents are listed in the Orange Book with respect to OPANA<sup>®</sup> ER tablets, which are the subject of NDA No. 21-610. Plaintiffs further admit that Impax requested that Plaintiffs provide it with a perpetual covenant not to sue for infringement of the '456 and '933 patents, and that they refused to do so. Plaintiffs further admit that they issued a joint press release on December 17, 2007, which press release speaks for itself. Plaintiffs deny the remaining allegations and implications of this paragraph.

81. Denied.

82. Denied.

83. Denied.

84. Denied.

85. Denied.

86. Denied.

### **AFFIRMATIVE DEFENSES**

1. Impax's counterclaim is premature and barred, in whole or in part, by 35 U.S.C. § 271(e)(5).

2. This Court presently lacks jurisdiction over any claim relating to issues concerning the infringement and validity of the '456 patent and the '933 patent.

3. Impax's counterclaim is barred, in whole or in part, because Impax purported to serve Impax Notices 1 – 6 (as defined in Plaintiffs' Complaint) pursuant to a valid ANDA at a time when Impax knew that it had no valid ANDA on file and accepted by FDA for substantive review.

4. Impax's counterclaim is barred, in whole or in part, because Impax Notices 1 – 6 (as defined in Plaintiffs' Complaint) are null, void and without legal effect, and none of those Notices commenced the 45-day period for filing a patent infringement action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

5. Impax's counterclaim is barred, in whole or in part, by the doctrines of unclean hands and/or equitable estoppel.

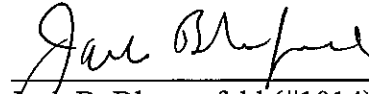
6. The Court should exercise its discretion to decline to hear Impax's counterclaim for declaratory judgment.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully pray that the Court deny all of Impax's requested relief and find in favor of Plaintiffs on all Counts, dismiss Impax's Counterclaim with

prejudice, award Plaintiffs the relief they seek in their Complaint, and award Plaintiffs their costs and attorneys fees, as well as such other relief as the Court deems equitable and just.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



Jack B. Blumenfeld (#1014)

Mary B. Graham (#2256)

Julia Heaney (#3052)

1201 North Market Street

P.O. Box 1347

Wilmington, DE 19899-1347

(302) 658-9200

*Attorneys for Plaintiffs Endo Pharmaceuticals Inc.  
and Penwest Pharmaceuticals Co.*

*Of Counsel:*

Martin J. Black

George G. Gordon

Ann M. Caviani Pease

Robert D. Rhoad

DECHERT LLP

Cira Centre

2929 Arch Street

Philadelphia, PA 19104

(215) 994-4000

*Attorneys for Plaintiff Endo Pharmaceuticals Inc.*

Robert J. Gunther, Jr.

Lisa J. Pirozzolo

James P. Barabas

WILMER CUTLER PICKERING HALE AND DORR LLP

399 Park Avenue

New York, New York 10022

(212) 230-8800

*Attorneys for Plaintiff Penwest Pharmaceuticals Co.*

January 14, 2008

**CERTIFICATE OF SERVICE**

I hereby certify that on January 14, 2008 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

Mary B. Mattterer  
MORRIS JAMES LLP

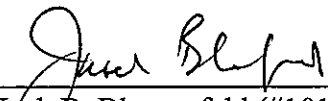
I further certify that I caused to be served copies of the foregoing document on January 14, 2008 upon the following in the manner indicated:

Mary B. Matterer, Esquire  
MORRIS JAMES LLP  
500 Delaware Avenue  
Suite 1500  
Wilmington, DE 19801

*VIA ELECTRONIC MAIL  
and HAND DELIVERY*

Asim Bhansali, Esquire  
KEKER & VAN NEST LLP  
710 Sansome Street  
San Francisco, CA 97111-1704

*VIA ELECTRONIC MAIL*

  
\_\_\_\_\_  
Jack B. Blumenfeld (#1014)